



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,009	02/20/2002	Lutz Weber	56937 (41925)	1331
21874	7590	03/01/2005	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			SHIAO, REI TSANG	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 03/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/081,009	Applicant(s) WEBER ET AL.	
	Examiner Robert Shiao	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on responses filed on 12/16, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This application claims benefit of the foreign application:
GERMANY 199 39 910.7 with a filing date August 23, 1999. However, the certified copy of the instant priority document has not been received. Applicants are requested to file the instant foreign priority document.
2. Claims 1-9 are pending in the application.

Responses to Election/Restriction

3. Applicant's election with traverse of Group I claims 1-9, in part, in the reply filed on December 16, 2004, is acknowledged. The traversal is on the grounds that no unreasonable burden is incurred by search of groups wherein certain of the delineated variables are defined more broadly than those recited in the Office Action. This is not found persuasive, and the reasons are given, *infra*.

Status of the Claims

4. Claims 1-9 are pending in the application. The scope of the invention of the elected subject matter is as follows:

Claims 1-9, in part, drawn to compounds and compositions of formula (I), wherein the variable X does not represent heterocycloalkyl or heteroaryl, and the variable X is not substituted with heterocycle or heteroaryl thereof; the variable Ar does not represent heterocycloalkyl or heteroaryl, and the variable Ar is not substituted with heterocycle or heteroaryl thereof; the variables R³, R⁴, R⁵, and R⁸ independently do not represent heterocycloalkyl or heteroaryl, the variables

Art Unit: 1626

R³, R⁴, R⁵, and R⁸ independently are not substituted with heterocycloalkyl or heteroaryl thereof; the variables and R⁶ and R⁷ independently do not represent heterocycloalkyl or heteroaryl, the aryl-heterocyclo moiety of aryl-heterocycloalkyl ring system of the variable R⁷ represents indole thereof; and when the variables R⁶ and R⁷ are members of a heterocycloalkyl ring system, the heterocyclo moiety represent piperazine thereof, the substituent of heterocycloalkyl ring system of R⁶ and R⁷ is as defined in claim 1 except: heterocycloalkyl ring system of R⁶ and R⁷ is not substituted with heterocycloalkyl or heteroaryl, and heterocycloalkyl ring system of R⁶ and R⁷ can be optionally substituted with 1,3-benzodioxol.

The above mentioned withdrawn compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition from the compounds of the elected invention. The withdrawn compounds contain varying functional groups (i.e., heteroaryl or heterocycloalkyl of the variable X) which differ from those of the elected invention such as oxazole, diazole, pyridine, morpholine, etc, which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classification of these functional groups in the U.S. classification system, i.e., class 548 subclass 215(+) (oxazole), class 548 subclass 300.1(+) (diazole), class 546 subclass 249 (+) (pyridine), class 544 subclass 106(+) (morpholine), etc. Therefore, again, the compounds which are withdrawn from consideration as being for non-elected

Art Unit: 1626

subject matter differ materially in structure and composition and have been restricted properly.

The Markush group set forth in the claims includes both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentably distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentably distinct compounds, also far too numerous to list individually. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner.

Claims 1-9, in part, embraced in above elected subject matter, are prosecuted in the case. Claims 1-9, in part, not embraced in above elected subject matter, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper and is therefore made **FINAL**.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

Art Unit: 1626

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

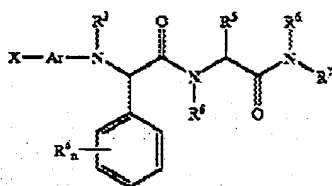
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,12 and 14 of Cappi et al. US 6,794,507. Although the conflicting claims are not identical, they are not patentably distinct from each other and reasons are as follows.

Applicants claim a compound/compositions of formula (I) as agents treating inflammation. The compounds are found on the pages 3-13 of the specification.

Cappi et al. claim a compound/compositions of formula (I) as agents treating inflammation,

Art Unit: 1626



, wherein the variable X represents $R^1-N=CH(-NH_2)-$, R^1 represents hydrogen, -OH, or $-C(=O)OR_2$, R_2 represents alkyl; the variable Ar represents arylene; the variables R_3 , R_5 , and R_8 independently represent H or alkyl; variables R_6 and R_7 together form a heterocycloalkyl ring system (i.e., piperazine), see columns 19-20. A number of examples have been specifically exemplified, see columns 10-18.

The difference between the instant claims and Cappi et al. is that the instant variable R_4 of formula (I) represents aryl or aralkyl, while Cappi et al. represents phenyl substituted with alkyl that may be substituted by -OH or -NH₂ at the same position.

One having ordinary skill in the art would find the claims 1-9 *prima facie* obvious because one would be motivated to employ the compounds/compositions of Cappi et al. to obtain instant compounds/compositions of formula (I), wherein the variable X represents $R^1-N=CH(-NH_2)-$, R^1 represents hydrogen, -OH, or $-C(=O)OR_2$, R_2 represents alkyl; the variable Ar represents arylene; the variables R_3 , R_5 , and R_8 independently represent H or alkyl; the variable R_4 represents aryl or aralkyl; variables R_6 and R_7 together form a heterocycloalkyl ring system (i.e., piperazine).

The motivation to make the claimed compounds/compositions derives from the expectation that the instant claimed compounds would possess similar

Art Unit: 1626

activities or function, i.e., agents treating inflammation, from the known Cappi et al. compounds/compositions to that which is claimed in the reference.

Objection

7. Claims 1-9 are objected to as containing non-elected subject matter heterocycloalkyl or heteroaryl, pyrazolyl, imidazolyl, etc. It is suggested that applicants amend the claims to the scope of the elected subject matter as defined on the pages 2-3 *supra*.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707.

The examiner can normally be reached on 8:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

Art Unit: 1626

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

R.S.

Robert Shiao, Ph.D.
Patent Examiner
Art Unit 1626

February 28, 2005

R. Desai

Rita Desai
Primary Patent Examiner
Technical Center 1600
Tel: (571) 272-0684

2/28/05